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Manufacturing Methodology for Personalised Symptom-Specific Sports Insoles

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Abstract

Orthotic insoles are used for numerous applications; they can be prescribed to treat medical conditions such as rheumatoid arthritis and to maintain the health of the feet of diabetic patients. Orthotic devices are also extensively used in sporting activities and can be used for improving skeletal function, thus enhancing the biomechanical performance of the user and subsequently providing a more economical gait. This paper focuses on the manufacture of sports insoles and provides a methodology for the design and manufacture of a personalised symptom-specific sports (3S) insole.

The framework includes the biomechanical assessment methods required for the effective prescription of a personalised insole. The requirements of a functional insole should relate not only to the geometry and condition of the foot but also the application in which it will be used. Different sports are played using specialised footwear, on varying surfaces and using diverse movements and so require an alternative design with regards to the geometry and materials used. Thus novel manufacturing methods are required and two examples are described, namely the cryogenic machining of soft foamed polymers to achieve suitable impact attenuation and the autoclaving of a carbon fibre composite material to produce a slim, rigid design.

Keywords

Sports insoles; Orthotics; CAD/CAM; Footwear; Mass Customisation

1. Introduction

The production of personalised orthotics has been established for many years. Recently, developments in the manufacture of orthotics in the form of CAD/CAM systems and scanning technology have enabled the acceleration of production [1]. Traditional plaster cast mould manufacturing methods, still employed by many podiatrists today, involve lengthy lead times and are comparatively expensive. These moulds are also often difficult to manipulate for a customer's required specification.

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Bespoke foot orthoses offer the customer a comfortable and functional insole which improves foot function by accommodating and controlling excessive motion during gait. A functional orthotic device can be fabricated over a mould taken of the foot which can be a plaster cast taken directly from the customer. However this is often time consuming and so an alternative approach is to use a scanning device to digitise the plantar surface of the foot, permitting the direct machining of hard polymers, such as polypropylene, from a CAD model [2, 3]. This subsequently reduces manufacturing times. Recent developments in the machining of soft polymers in the form of cryogenic machining allow the direct machining of semi-rigid devices [4], which will be of benefit to the sporting sector due to their ability to improve function and attenuate impact.

Carbon fibre reinforced plastic (CFRP) insoles may also be manufactured to provide a lightweight, space-saving device which is of increasing importance in many sports. For example, football boots are evolving rapidly, with new designs offering slim fitting and lightweight products which often contribute to the development of bony growths such as osteophytes, possibly as a consequence of poor boot design and protection [5]. Many devices simply cannot fit into current boot designs and even if they could, they would have a large impact on the overall weight of the boot and so a CFRP insole provides a slimmer profile due to its stiffness and rigidity.

This paper presents an innovative methodology for the development of a symptom-specific sports (3S) insole. The initial part of the paper provides a review of foot orthotic design and manufacture, including a classification of current designs and an explanation of the common biomechanical requirements of orthotics. The second part outlines the major activities relating to the framework for the design and manufacture of a 3S insole. This includes details on the assessment methods, design process, materials selection and cryogenic machining and autoclaving of CFRP parts as suitable manufacturing methods.

2. Foot Orthoses

Taken from the Greek “ortho”, meaning “straight”, an orthosis is a device that is applied externally and is used to improve quality of movement. The orthosis aims to correct biomechanical and postural inaccuracies, thus improving function. Orthoses can be applied to many parts of the body, mainly to the limbs such as knee-ankle-foot orthoses (KAFO) and upper extremities. This paper will concentrate on foot orthoses as these are the most prevalent orthotic devices and can be prescribed for a number of reasons such as to relieve pressure or pain in the foot, as a treatment to reduce the risk of ulceration for diabetic patients and to correct biomechanical inefficiencies and deformities [6-8].

A foot orthotic is a correctional insert, placed within the shoe in the form of an insole. Hunter *et al.*[9] describe a foot orthotic as “a device that is placed in a person’s shoe to reduce or eliminate pathological stresses to the foot or other portions of the kinetic chain” including stresses caused by muscular-skeletal deformities and an inability to shock absorb. Orthotics and shoe inserts are often prescribed for sporting applications in

an attempt to achieve correct skeletal alignment, thus reducing the risk of overuse injury due to poor biomechanics. Nigg *et al.* [10] suggest that orthotics can be prescribed in an attempt to minimise muscle work. If an orthotic intervention supports a more economical movement pattern then it is fair to assume that stabilising muscles will have to work less than when inefficient movements are used.

Orthotics can be classified in many different ways, these methods include their rigidities, production methods and applications. Orthotics classified due to their physical rigidity can be soft, semi-rigid or rigid devices [7, 10-13], each with their documented advantages; a review by Clark *et al.* [14] indicate that a rigid orthosis decreases forefoot and rearfoot pain in subjects with early onset of rheumatoid arthritis. The rigid devices also decrease the level of foot deformity in rheumatoid arthritis with hallux valgus. It is a common belief among podiatrists that a correctly fitting rigid device has no need for impact attenuation due to the correct biomechanical alignment of the skeletal structure. However, there is also contrasting opinions that suggest impact absorption should be a feature of sporting orthotics [13], due to the large forces experienced at the foot during physical activity, which can be up to five times body weight [15].

In terms of their manufacturing methods, there are three basic types of foot orthoses [16];

- Prefabricated – these are mass produced and can be bought off the shelf; they typically provide general arch support or cushioning to areas of the foot without any specific personalised features and are the cheapest to purchase.
- Customised – a customised orthosis is typically a modified prefabricated component. Often these can be produced through a modular design such as the addition of a metatarsal pad to relieve pressure in a specific area, or the introduction of a heel lift for the treatment of leg-length discrepancies. These features can be added to a polypropylene off-the-shelf shell. A cover is then applied to the whole device for comfort, usually either a low density foam or leather material.
- Custom-moulded – an orthotic manufactured from a cast or mould of the patient's foot. These often provide the best fitting orthotics and give the best results. A custom moulded orthosis is bespoke to the user.

These types can be further categorised into accommodative or functional orthoses. An accommodative, or total contact device, will accommodate and protect a rigid foot or a specific deformity without correction, whereas a functional device provides joint stability, controls motion and corrects the function of the foot. The mould taken from the foot is often adapted to enhance alterations made to the final device; for example taking material off a positive cast will increase the arch height of the orthotic. There are many types of foot orthotic available and these can be prescribed and used for a number of different purposes. The required use of an orthotic insole will fall into one of three main categories. These are then subdivided into further groups, outlined in figure 1. Orthotics used for sports; these are most commonly manufactured for running, other

sporting examples include insoles for court sports such as basketball. Orthoses are also prescribed for medical purposes such as the prevention of sores for diabetic patients and also the treatment of rheumatoid arthritis (R.A.) by realigning foot deformities. The final subsection is comfort orthotics, these are designed for dress shoes and can be shaped into a slim design to fit into narrow shoes. Currently there are orthotics available for sports, however these do not offer specificity to movements experienced in the chosen sport and so an improved assessment and prescription method is required.

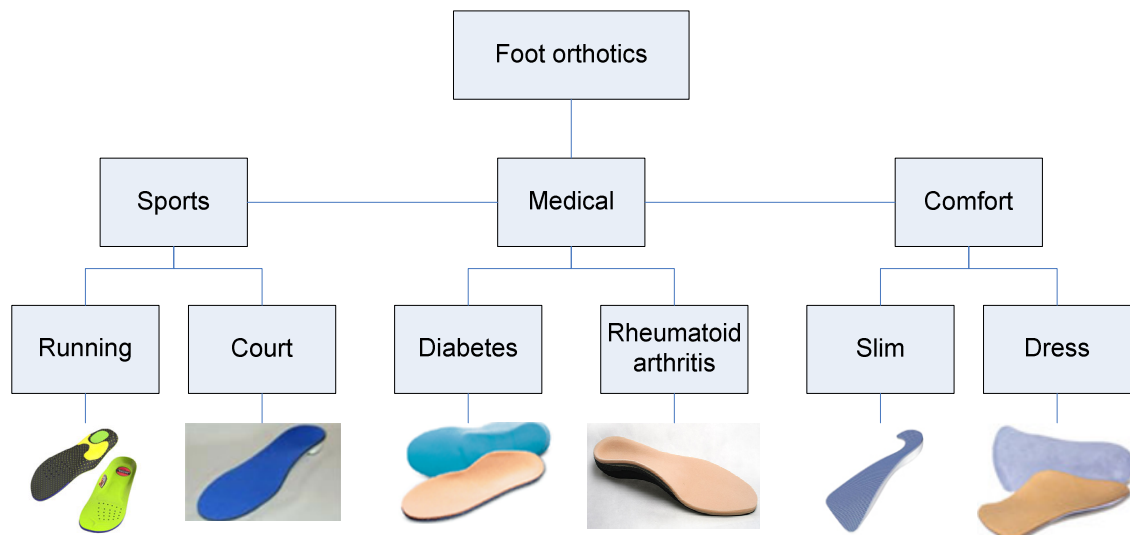


Figure 1: Classification of foot orthotics

Different insoles require different manufacturing methods to suit their production volume. A prefabricated soft orthotic may well be injection moulded which involves the machining of a pre determined mould that is subsequently used for the mass production of insoles. This is not a personalised solution and so will not offer customer-specific biomechanical correction. The injection moulding of personalised products is not a viable process as for each customer a new mould would be required. Thus the adaptation of a prefabricated device for a customised insole is often the best practice for a podiatrist. A best fit shell is chosen based on factors such as foot size and arch height required. The shell material determines the ultimate rigidity of the device. A cover is then placed over the top for comfort, this is commonly a layer of ethylene vinyl acetate (EVA) foam. EVA foams are very versatile and can be produced in a range of densities and so are ideal for providing both impact attenuation and comfort.

3. Methodology for the Design and Manufacture of a 3S Insole

In order to prescribe an athlete with functional orthosis or insole, a thorough biomechanical assessment must be undertaken. Currently, many clinics are utilising the development of scanning equipment to digitise the profile of the feet of subjects in a number of sports. The movements and stresses experienced in the feet during differing activities are characteristic of each sport i.e. a sharp change of direction or kicking a ball. Eils *et al.* [17] showed that when kicking, a footballer shifts the load through the

planted foot to the lateral portion of the foot in contrast to forward running, where the medial border takes the predominant load. This suggests that different athletes will be susceptible to varying forces through the feet depending on the prevalent actions undertaken in the sport. The stresses experienced by a football player may well differ greatly to that of a long jumper or tennis player. This could be due to a number of factors such as the playing surface and the type of footwear worn, Santos *et al.* [18] reported an increase in forces and pressures experienced when wearing football boots in comparison to trainers.

These factors can all be collated in order to provide an accurate prescription for an athlete in terms of a functional orthosis. The insole may be prescribed based not only on the geometry and biomechanical requirements of the foot but also a consideration of the sport played. For example, if a high rigid arch was applied to a footballer, this could be detrimental in some cases as when kicking a ball, the insole will apply further pressure to the natural weighting on lateral portion of the foot. The plantar pressures experienced by athletes when performing sport-specific movements may be characterised to ascertain trends in loading patterns thus providing the information to influence design and materials knowledge bases. These results provide parameters on which to base structured prescriptions along with foot anatomy for the geometry of the insole design. The testing method provides a structure suitable for application across many sports activities and this is described in section 3.1.

3.1. IDEF0 diagrams

The following Integration DEFinition for functional modelling (IDEF0) diagram shown in

figure 2 presents the structure and contributing factors for the design and manufacture of a 3S insole. The diagram shows the inputs, outputs, control factors and mechanisms relating to the design and manufacture activity.

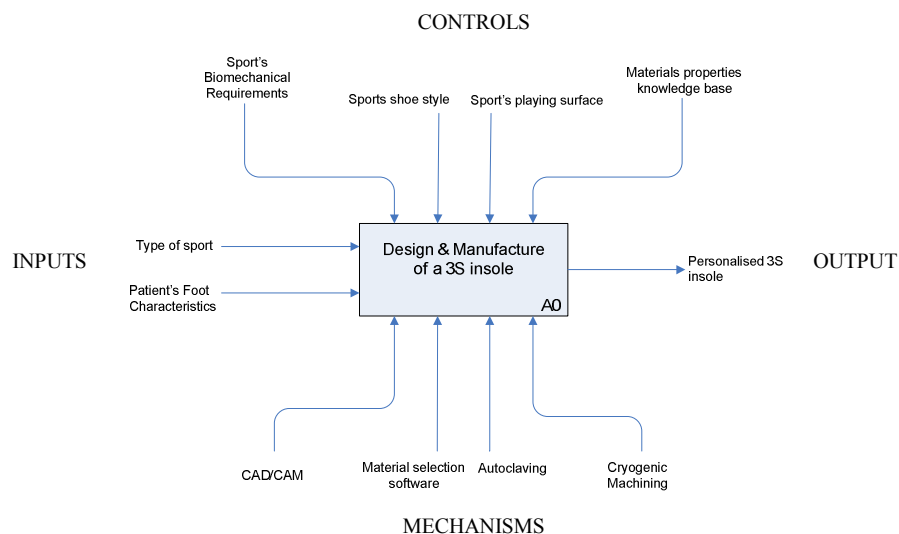


Figure 2: IDEF0 representation of the design and manufacture of a 3S insole

Figure 3 shows the second level of the IDEF0 diagram and displays the major sub-activities involved in the production of a 3S insole. The activities are described in the sections 3.1 to 3.4 below.

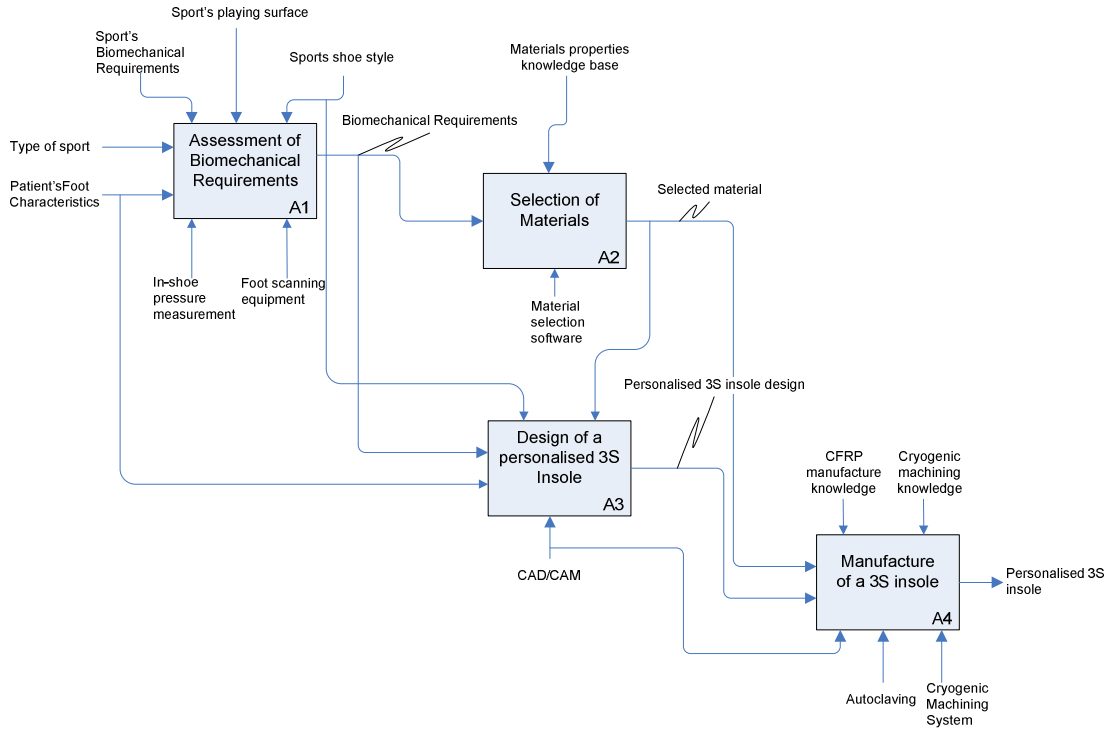


Figure 3: Expanded IDEF0 diagram for the design and manufacture of a 3S insole

3.2. Assessment of Biomechanical Requirements

It is widely accepted among podiatrists that an orthotic device should place the foot into a neutral subtalar joint (STJ) position [7, 10, 19, 20], thus correctly aligning the skeleton during the midstance phase of gait. By introducing this foot position, the amount of inversion/eversion experienced at the foot is reduced; subsequently the amount of external/internal rotation transferred to the knee joint is also lessened.

Orthotic devices can significantly reduce both the symptoms of skeletal deformities and disease, such as diabetes and rheumatoid arthritis, and help to prevent injuries higher up the kinetic chain [21, 22]. The correct alignment of the skeleton is a major function of a corrective insert and a correct posture is essential for a successful sports performance. By achieving an economical and effective gait, an athlete will potentially expend less energy. There has been much research into the performance enhancing properties, or the fatigue related effects of materials used in running shoes [23-26] and these principles can be applied to the materials used in orthoses manufacture, thus helping to achieve a fluent gait.

There are many foot conditions that require orthotic intervention, too many to document in this paper. Common problems such as over-pronation can easily be assessed by the naked eye by simply observing the subject walking or running. More complicated assessments and diagnoses are currently undertaken by clinicians such as podiatrists or physiotherapists. It is clear that a standardised assessment method is required to produce reliable and repeatable results [27]. Thompson *et al.* [28] reported an inter-clinician variation with respect to the foot health assessment of three diabetic patients thus resulting in potentially different care pathways. New technologies such as scanning equipment, used to capture an accurate representation of the plantar surface of the foot, and in-shoe pressure measurement systems, which measure the pressure experienced by the foot during sport-specific movements, provide a reliable and repeatable method to gather the required information for accurate insole prescription. Perry and Lafortune [29] documented an increase in impact loading at the foot when running in comparison to walking when examining the effects of pronation restriction through orthosis intervention. This would suggest that with even a small change in activity such as walking to running a different orthosis prescription should be specified. Thus moving through different sports that will require completely different movements will almost certainly require varying prescriptions. These testing methods will also provide the clinician with reliable tools for the evaluation of the insole design.

The assessment of the biomechanical requirements of the athlete will include inputs both from the patient's foot characteristics and also factors from the type of sport the insoles will be manufactured for, as shown in activity 1 (A1) in figure 3. The controls from the sport will be the general biomechanical requirements of the sport, for example a sport that is played on a hard surface will require impact attenuation which will be the same for any athlete. Also the type of footwear used for an individual sport will affect the requirements of the athlete; a tight fitting shoe will need a slim design for space-saving purposes. This information is collected before selecting the materials and designing the insole. As mentioned, three dimensional foot scanning equipment can be used to create an accurate image of the foot and this, along with in-shoe pressure measurement to ascertain the peak pressure locations experienced by the foot, will support the assessment process in order to give an appropriate prescription.

3.3. *Selection of Materials*

There are numerous methods for the fabrication of foot orthoses which depend on the material chosen. As mentioned there are a number of classifications for the devices such as rigidity and function and the physical properties of the orthotic materials contribute to these characteristics [30]. Whilst there are contradictions over classification methods, there is a general agreement between professionals with regard to the important physical characteristics within orthotic fabrication. These include their response to temperature, elasticity, hardness, density, durability, flexibility, compressibility and resilience [16, 31]. Density and hardness are of particular interest as it is these attributes that affect the impact attenuation of the device; a high density material will have little cushioning and so will provide a rigid, often controlling structure whereas a material of low density will

absorb shock. The hardness of the material reflects its resistance to indentation, thus a hard material will not shock absorb.

The materials commonly used for orthotic manufacture are:

- **Plastics:** polypropylene is a good example of a semi-rigid or rigid material and exists just above its glass transition temperature (T_g) under operating conditions and so remains controlling *in situ*. The rigidity of the device will be controlled by the thickness of the sole plate.
- **Foamed materials:** such as polyurethanes and EVAs; these can either be open or closed cell foams consisting of a continuous polymer phase enclosing a discontinuous gas phase (pockets of gas). Open celled foams, as their name suggests allow interaction between the pockets of air whilst in a closed cell foam the gas is enclosed within the polymer cells, thus providing a water-tight material. Polyurethane is often used as a top cover or extension for a customised orthotic due to its durability and ease of manufacture. EVA, like polyurethane is used extensively and successfully in the midsoles of sports shoes [23] and so is an obvious candidate for use in orthoses. It has been documented that a high density EVA ($300\text{-}400\text{kg/m}^3$) is a clinically desirable damping material, possessing properties most suitable for motion control [30].
- **Carbon Fibre Reinforced Plastics (CFRP):** Orthoses manufactured using CFRPs have the benefit of an extremely high stiffness to weight ratio. Companies such as Blatchford in the UK and Proteor in France manufacture carbon fibre orthoses, although they mainly concentrate on knee-ankle-foot orthoses (KAFO) and ankle-foot orthoses (AFO). CFRP insoles can provide space saving solutions for shoe styles that are less accommodating, for example, a football boot with a very narrow sole plate or a dress orthotic for ladies high heel shoes. The main disadvantage to using carbon fibre is that once the device has been formed, it cannot be readjusted due to the thermosetting resin matrix.

The choice of the material for the design of a 3S insole is critical for its functionality. An insole that is too rigid will offer no impact attenuation whilst a soft material will not provide the athlete with enough support. Figure 3 shows that the materials selection process will take place in conjunction with the design of the geometry of the insole. This depends on the sport played and on the pressures on the foot during the movements experienced within the sport. The selection of the material will then have an impact on the design, such as the thickness of the insole; a less dense material may require a greater thickness to achieve the desired rigidity.

In terms of the methodology proposed in figure 3, the materials selection activity will require inputs from the results of the biomechanical assessment and the patient's foot characteristics, with a knowledge base of material properties offering control. A materials selection software package such as Granta's CES EduPack [32] offers materials properties and also provides selection criteria in the form of Ashby diagrams

so as to ensure a suitable material for the required use is chosen. The outputs from this activity (A2) will subsequently provide a control for the design process (A3).

3.4. Design of a Personalised 3S Insole

Intelligent design of the 3S insole will require a comprehensive knowledge base for a number of areas. Figure shows an outline for the prescription method for a 3S insole. Initially, a comprehensive biomechanical evaluation of the patient will be carried out based on the requirements of the subject's feet, the sport played and also the sports shoes to be used. A standard assessment method will be employed in order to achieve reliable and consistent results. This information will then be added to the database consisting of knowledge gained of the requirements of the chosen sport, material type and the properties possessed by suitable materials. The material choice will directly affect the choice of rigid or semi-rigid manufacturing processes. The patient's information can be stored thus allowing for new insole designs to be manufactured without the need for numerous reassessments. Further to this the materials will influence the insole design and vice-versa. A design knowledge base will be built up as more products are manufactured and the patient's foot geometries and biomechanical requirements will be stored for future use.

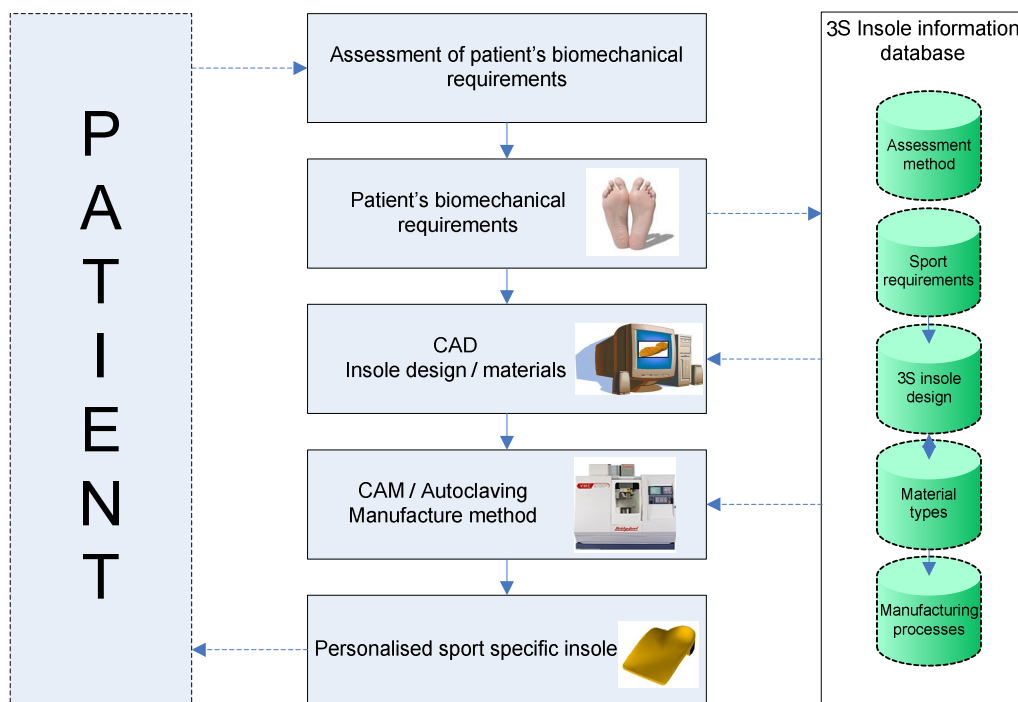


Figure 4: Prescription method for a 3S insole

The solid lines in the diagram represent the necessary steps in order to produce a 3S insole whilst the broken lines show where knowledge transfer will take place. In terms of the design activity (A3) in figure 3, the controls are produced from the results of

materials selection process and from the design of the sports shoe the insole will be placed into. Certain footwear designs have specific geometries relating to the bottom surface of the insole. If a new bespoke insole is to replace the generic one then this bottom surface must be replicated to ensure correct fitting is achieved. The inputs into the activity are the foot characteristics and biomechanical requirements of the subject. This is achieved through the use of a CAD system which utilises the results of the assessment of the foot scan and pressure measurements.

3.5. Manufacture of a 3S Insole

One of the major aims for the design of the 3S insole is the rapid manufacture of a bespoke product, thus delivering a mass personalised solution. The ability to accurately scan the foot in order to produce a 3 dimensional image has enabled precise CAD representation of the foot to be formed. From this, a CAD model of an insole can be designed, which considers the geometry of the aligned foot and the shoe in which it is to be placed. The two manufacturing techniques proposed are the machining of rigid and semi-rigid materials and the laying up and autoclaving of CFRP.

3.5.1. Cryogenic Machining

Traditionally the most common production method for soft products has been through the use of injection moulding. However, this is not an economically viable method for personalised parts as a new mould has to be manufactured for every customer. The process of cryogenically freezing and machining of soft polymer foams allows the custom manufacture of semi-rigid and soft insoles.

In order to facilitate the machining of low density polymer foams, there are key characteristics of the substrate that must be altered, most notably its stiffness. This is achieved by freezing the material below its glass transition temperature (T_g), which is the temperature required to change an amorphous solid from a soft material to a brittle one, allowing it to be machined. The T_g of polymers may be measured using Dynamic Mechanical Thermal Analysis (DMTA). A dynamic mechanical analyser is used to monitor the dynamic property changes over a range of temperatures at a fixed frequency of $\sim 1\text{Hz}$ to obtain the mechanical responses of a material. Figure 5 shows a typical results graph for a neoprene foam. The T_g of -61°C is characterised by the intersection of the gradients of the initial shallow and steep stages of the modulus values.

The thermal mass of materials differs and they freeze at different rates with respect to T_g . With foamed materials, the density of the material will have an impact on the freezing characteristics due to the pore size reflecting the amount of gas within the foam. The gas inside the cells act as a thermal insulator and so would hamper the freezing of the material.

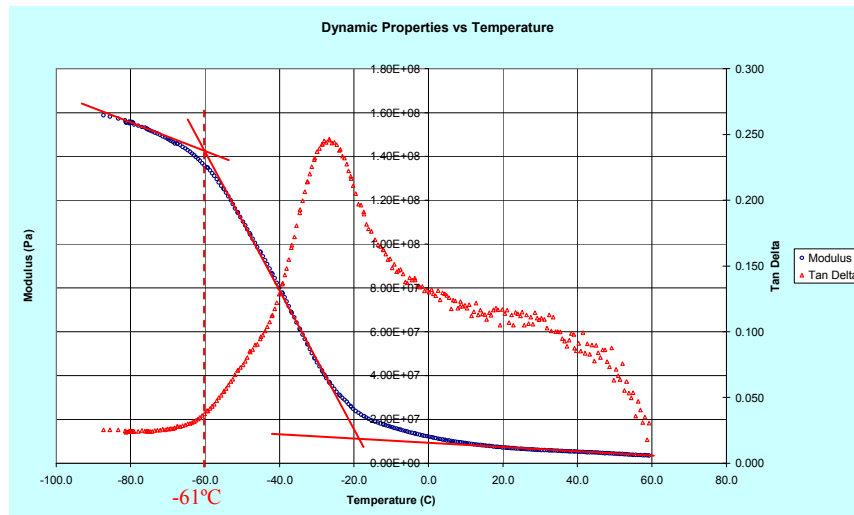


Figure 5: Glass transition temperature of a neoprene foam

Liquid Nitrogen is used as a cryogen to freeze polymer foams using various fixtures to find the most effective way of reaching and maintaining a temperature below T_g [4]. By freezing a foamed material, there is scope to machine a bespoke, one-off part directly from a CAD designed insole. Due to the stiffness of the foamed polymer when below its T_g , it is possible to machine thin sections that would otherwise tear and deform when dry machined and also allows for dual sided machining, resulting in the ability to produce a bespoke insole with respect to the geometries of the foot and the shoe in which it is placed. The CAD design can be produced by utilising a scanned image of the plantar surface of the foot, either directly from the foot itself or a scan or data collection from a cast of the foot using a coordinate measuring machine (CMM). These data points are then used to create a sculptured surface CAD model which can be manipulated as required to produce the required geometry for the insole design.

As the cryogenic technologies evolve and knowledge of useable materials increases, the knowledge database as shown in figure 4 will expand, affecting both materials selection and insole design. Cryogenic machining makes up one mechanism for the manufacture of a 3S insole, another manufacturing process is autoclaving which is outlined below.

3.5.2. Manufacture of a Carbon Fibre Orthotic

The processes involved in the production of an individual carbon fibre part, i.e. hand lay-up and vacuum bagging involve low tooling costs whilst producing extremely good results [33]. Pre-impregnated (prepreg) composite materials are used for the production of the insoles. A layer of unidirectional material for increased directional stiffness can also be used.

Laminates are laid up onto the plantar surface of a positive cast of a foot to produce a thin and stiff lightweight insole. Reinforcing areas may be added to provide further stiffness in specific areas where required, illustrated in figure 6. The laminates are first

cut into rough shapes and heated to warm the resin thus making the material more pliable allowing the material to be draped accurately onto the cast [34].



Figure 6: Laying up process

The construction is then placed under pressure in a vacuum bag in order to bond the layers together before being exposed to a temperature and pressure cycle according to the material properties in an autoclave oven to cure the resin matrix. The final product is then ground down to a finished orthotic shape and finished to fit within the desired shoe, shown in figure 7.



Figure 7: Final orthotic shape

The final stage of the orthotic design is to evaluate its performance. This can be achieved through a number of methods;

- The perception of the subject; this is imperative as the athlete will be using the device. Hence a functional device, although intending to correct skeletal function and provide motion control, must not compromise comfort. It must be noted however that a rigid, functional orthotic may temporarily affect the proprioception of the athlete and so this initial phase of re-educating the skeletal movements must be tolerated.

- The success of the biomechanical correction intended; this may be assessed using gait analysis techniques involving a reassessment of plantar pressure distribution and the effect of the insole on skeletal alignment.
- Mapping the insole to the geometry of the foot cast; the finished orthotic can also be offered up to the original plaster cast mould of the foot to see whether or not the geometry of the plantar surface of the foot is adequately mirrored by the orthotic device. This is carried out after the final grinding of the insole, shown in figure 8.



Figure 8: Carbon fibre orthotics on plaster casts

4. Discussion

Orthotics used for physical activity improve skeletal alignment, thus reducing the risk of overuse injuries as a result of poor biomechanics. The use of personalised insoles for sporting applications provides the athlete with an improved gait, thus increasing efficiency when completing the activities required of the sport. The manufacturing framework outlined in this paper will allow the manufacture of a suitable insole for an athlete with regard to their own biomechanical requirements and also the physical demands of the sport.

The design of a 3S insole is reliant on the merger of a number of technologies. By introducing plantar pressure measurement of sport specific movements synonymous with the activities the insert will be used for, an improved prescription in terms of the functionality of the device in situ will be achieved. The design draws on knowledge of material properties and manufacturing techniques as well as correct biomechanics to achieve correct skeletal alignment resulting in a more economical gait.

Cryogenic machining is a novel method for the personalised manufacture of semi-rigid and soft insoles. The technology allows for dual side machining of foamed polymers which in turn enables the manufacture of insoles not only bespoke to the foot of the athlete but also to the desired footwear. CFRP manufacture allows the production of

high modulus, slim profile insoles. These can be utilised in footwear in which space is at a premium and high rigidity is still required.

Many current sports orthotics are rigid devices with a semi-rigid or soft cover laid on top. The advantage of the 3S insole is that it can be manufactured from a variety of different materials depending on the required rigidity and geometry.

5. Conclusion

The methodology presented in this paper offers the following benefits:

- The manufacture of personalised, functional insoles that are not only specific to the biomechanical needs of the customer but also the sporting environment in which they operate results in improved and effective gait, thus decreasing the risk of injury.
- A correctly prescribed 3S insole provides the athlete with a more economical gait, thus helping to prevent the onset of fatigue through muscular stress.
- The manufacture framework presents a methodology for the prescription of a 3S insole, detailing suitable manufacturing methods for various materials.
- A reliable and repeatable assessment process involving the evaluation of plantar pressure distributions and three dimensional scanning of the feet will allow for the prescription of a suitable insole.
- Cryogenic machining enables the high quality manufacture of low modulus materials such as foamed polymers. The ability to select foams of varying densities allows the desired level of impact attenuation to be achieved.
- Direct CNC machining from CAD models produced from the scanning and assessment methods enable rapid manufacture of personalised products, eradicating the need for lengthy processes such as cast manipulation and injection moulding.

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